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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/207,649	12/08/1998	SUSAN LINDQUIST	17481-004001	7099

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/207,649	LINDQUIST, SUSAN	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7-20,22 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7-20,22 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's response of March 03, 2007 to the office action mailed on December 08, 2006 has been fully considered. No amendments to the claims have been presented with the response.

2. Claims 1, 3, 7-20, 22 and 37 are pending and under examination in the instant office action.

3. Applicant's arguments filed on March 03, 2007 have been found to be persuasive to overcome the rejections of record under 35 USC § 103.

4. After further consideration, the following new grounds of rejections are as follows.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 7-11, 14-20, 22 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 7-11, 14-20, 22 and 37 are directed to a method of identifying a candidate substance that inhibits the aggregation of a mammalian aggregate-prone amyloid protein in a yeast cell. Claims 1 and 7 specifically recite a mammalian aggregate-prone amyloid peptide as a

part of a chimeric protein to be expressed in a yeast cell as a necessary component to practice the instant claimed method. The claims do not require that the mammalian aggregate-prone amyloid protein possesses any particular conserved structure or other disclosed distinguishing feature As such, the claims encompass a genus of polypeptides that is defined only by mammalian origin. However, the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a PrP, prion protein, and β-amyloid polypeptide. The claims, however, encompass a mammalian aggregate-prone amyloid protein. Thus, the claims are not limited to a protein with a specific conserved amino acid sequence or other distinguishing feature. The claims only require that the aggregate-prone amyloid protein be a mammalian protein. The specification only describes two proteins of the recited genus and fails to teach or describe any other protein which meets the limitation of a mammalian aggregate-prone amyloid protein.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of a mammalian protein. The instant specification presents the following definition of the term "aggregate-prone amyloid protein": "any protein that is able to form an

amyloid or amyloid-like deposit" (p 5 of the specification). With respect to the mammalian aggregate-prone amyloid proteins, the specification discloses two species of the genus, which are PrP and β-amyloid polypeptide (fourth paragraph at p. 5). The specification does not provide a complete structure of those polypeptides that are mammalian aggregate-prone amyloid proteins and fails to provide a representative number of species for the recited genus. There is also no description as what represents "an aggregate forming domain of a mammalian aggregate-prone amyloid protein", see claim 7. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the genus of mammalian aggregate-prone amyloid proteins.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of protein, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993).

The instant situation is directly analogous to that, which was addressed in *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*, 18 U.S.P.Q. 2d, 1016 (Fed. Cir. 1991). The court held that:

"A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and describe how to obtain it. See *Oka*, 849 F.2d at 583, 7 U.S.P.Q. 2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated".

See also *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. One cannot describe what one has not conceived. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the method of encompassing PrP and β-amyloid polypeptide, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3, 7-20, 22 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is vague and indefinite for recitations "mammalian aggregate-prone amyloid protein" and "mammalian aggregate-prone amyloid peptide". It is not clear and cannot be determined from the claim or the instant specification as filed if these limitations encompass the same molecular embodiment or different embodiments. Therefore, the claim is being incomplete for omitting essential cooperative relationships of elements, such elements include "mammalian aggregate-prone amyloid protein", "mammalian aggregate-prone amyloid peptide" and "chimeric aggregate-prone amyloid protein".

Specifically, the instant specification defines the term "aggregate-prone amyloid protein" as "any protein that is able to form an amyloid or amyloid-like deposit" (p 5 of the specification). There appears to be no specific definition of a "mammalian aggregate-prone amyloid peptide" presented within the specification. The art defines amyloid peptide, Aβ, as a product of proteolytic cleavage of APP, the β-amyloid precursor protein that is encoded by a gene on human chromosome 21 (see Haass et al., 1993, Cell, Vol. 75, pp. 1039-42, p 1039, first column specifically). The precise amino acid sequence of Aβ is well known and is different from the amino acid sequence of Prion protein PrP, which is encoded by a gene located on chromosome 20 (see Kretzschmar et al., 1986, DNA, Vol. 5, No. 4, pp. 315-24, p. 3120, first column specifically). Because claim 1, as currently presented, recites multiple aggregate-prone amyloid

molecular embodiments, the method steps are not obvious. Furthermore, because the structure of these different amyloid proteins/peptides, which comprise the chimeric protein is not defined, the relationship between "amyloid peptide" and PrP recited in dependent claim 3 is not clear as well. Clarification is required.

10. Claim 13 is vague and indefinite for recitation of limitation "about amino acids 1-42". Although the term "about" in a claim is inherently vague and indefinite, its use is appropriate when employed to limit a value, which is composed of indefinitely divisible units such as inches, meters and grams where it is impractical to produce an item which has exactly the dimension recited. Even if one could practically produce an item, which is exactly 1 inch in length, the length of that item is conditional upon the temperature at which it is measured. However, when defining an invention in terms of indivisible numerical units such as the number of nucleotides in a nucleic acid, the number of amino acids in a polypeptide or the number of legs on a chair or table, the term "about" is unacceptably vague and indefinite since it is practical to employ a term, which possesses the required precision. If, for example, it is Applicant's intension that the claims should encompass a polypeptide of more than a certain amount of amino acids in length then this is exactly what the claim should recite. Whereas one would reasonably interpret the term "about one inch" as encompassing any value from 0.90 inches to 1.10 inches one would not know if the term "about 1-42 amino acids" would exclude 2 to 43 or 44 amino acids.

11. Claims 3, 7-12, 14-20, 22 and 37 are indefinite for being dependent from indefinite claim.

Allowable Subject Matter

12. Claims 3 and 12 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

March 27, 2007